Life Spine®

K073480

510(k) Summary

510(k) Summary – Life Spine Cross Connector

Submitted By:

Life Spine
2401 W. Hassell Road, Suite 1535
Hoffman Estates, IL 60169
Telephone: 847-884-6117
Fax: 847-884-6118

JAN - 4 2008

510(k) Contact:

Rebecca Brooks
Life Spine
2401 W. Hassell Road, Suite 1535
Hoffman Estates, IL 60169
Telephone: 847-884-6117
Fax: 847-884-6118

Date Prepared: December 10, 2007

Trade Name: Life Spine Cross Connector

Common Name: Appliance, Fixation, Spinal Interlaminal

Classification: 888.3070 Pedicle screw spinal system

Device Product Code:

MNH, 21 CFR 888.3070, Class II
MNI, 21 CFR 888.3070, Class II
NKB, 21 CFR 888.3070, Class III

Predicate Device: Arx-Link™ Cross Connector K070995

Device Description:

The Life Spine Cross Connector is a titanium alloy, multiple component system comprised of a variety of non-sterile single use components that allow the surgeon to build a spinal implant construct. The system is attached to the vertebral body by means of screws to the non-cervical spine.

The Life Spine Cross Connector is available in various sizes. This device is an addition to the current systems (K070995) and therefore is fully cross-functional within the current systems.

Life Spine®

Intended Use of the Device:

Internal fixation implants are load-sharing devices intended to stabilize and maintain alignment until normal healing occurs. Implants are not intended to replace normal body structures or bear the weight of the body in the presence of incomplete bone healing.

The ARX® Spinal System, when properly used, is intended for posterior pedicle screw fixation of the non-cervical posterior spine in skeletally mature patients. It provides stabilization and immobilization of spinal segments as an adjunct to fusion.

When used as a posterior spine thoracic/lumbar system, the ARX® Spinal System is indicated for one or more of the following: (1) degenerative disc disease (is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies), (2) trauma (i.e. fracture or dislocation), (3) curvatures (scoliosis, kyphosis, and/or lordosis), (4) spinal tumor, (5) failed previous fusion (6) pseudarthrosis, (7) spinal stenosis, (8) spondylolisthesis.

Material:
Manufactured from medical grade titanium alloy described by ASTM F136 (Ti 6AL-4V-ELI) implant grade titanium alloy.

Performance Data:
Biomechanical testing in accordance with ASTM F1717 was conducted to demonstrate substantial equivalence.

Substantial Equivalence:
The Life Spine Cross Connector was shown to be substantially equivalent to previously cleared devices in indications for use, design, function, and materials used.

2401 W. Hassell Road Suite 1535 • Hoffman Estates, IL 60169 • www.lifespine.com • p 847.884.6117 • f 847.884.611

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN - 4 2008

Life Spine
% Ms. Rebecca Brooks
2401 W. Hassell Road
Suite 1535
Hoffman Estates, IL 60169

Re: K073480
Trade/Device Name: Life Spine Cross Connector
Regulation Number: 21 CFR 888.3070
Regulation Names: Pedicle screw spinal system
Regulatory Class: III
Product Code: NKB, MNI, MNH
Dated: December 10, 2007
Received: December 11, 2007

Dear Ms. Brooks:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041 or (240) 276-3150 or the Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Life Spine®

Indications for Use

510(k) number (if known): _____

Device Name: Life Spine Cross Connector

Internal fixation implants are load-sharing devices intended to stabilize and maintain alignment until normal healing occurs. Implants are not intended to replace normal body structures or bear the weight of the body in the presence of incomplete bone healing.

The ARX® Spinal System, when properly used, is intended for posterior pedicle screw fixation of the non-cervical posterior spine in skeletally mature patients. It provides stabilization and immobilization of spinal segments as an adjunct to fusion.

When used as a posterior spine thoracic/lumbar system, the ARX® Spinal System is indicated for one or more of the following: (1) degenerative disc disease (is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies), (2) trauma (i.e. fracture or dislocation), (3) curvatures (scoliosis, kyphosis, and/or lordosis), (4) spinal tumor, (5) failed previous fusion (6) pseudarthrosis, (7) spinal stenosis, (8) spondylolisthesis.

Prescription Use _x_	And/Or	Over-the-Counter Use ____
(Part 21 CFR 801 Subpart D)		(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

FOR M. MELKERSON

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K073480